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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,182	09/21/2005	Mats Inganas	P02774US1	8048

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EXAMINER	
HURST, JONATHAN M	

ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
08/18/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/550,182	INGANAS, MATS	
	Examiner	Art Unit	
	JONATHAN M. HURST	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 3-12 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Mian et al. (US 6,319,469).

Regarding claims 1, 4, and 15 Mian et al. discloses a collection of one or more microfluidic devices which together carry a plurality of microchannel structures each of which comprises a reaction microcavity in which there is a solid phase with an immobilized affinity ligand L, (See Fig. 1A, Fig. 1C, Fig. 17L, and Col. 43 Lines 25-40), wherein

(i) the plurality comprises two or more different sets of microchannel structures, (See Fig. 17L where each disk layer comprises a set of different channels Fig. 17A where disk contains sets of different channels and Col. 33 Lines 33-36 where a device performs a set of procedures or multiple embodiments of the same procedure), and

(ii) the affinity ligand L is directed to the same counterpart (binder, B) independent of set, and (See Col. 33 Lines 33-36 where sets of the same procedure are performed) and

(iii) the sets differ with respect to

a) the capacity for binder B per reaction microcavity and/or the capacity per unit volume of the solid phase in a reaction microcavity, and/or (See Col. 8 Lines 30-35 where reservoirs act as microcavity and sizes differ

depending upon embodiment and thus have different capacities for reagents) and

b) the base matrix of the solid phase between the sets but are equal within each set. (See Fig. 17L where base is different for each set of channels)

The microchannels, reaction microcavity, and the solid phase have surfaces exposing a plurality of polar functional groups such that said surfaces are hydrophilic (See Col. 14 Line 45 – Col. 15 Line 45 where the walls of the microchannels and of microcavities (solid phase) are modified to have hydrophilic surfaces with polar functional groups to improve adsorption of specific materials) especially since the materials used are modified to have hydrophilic groups and thus the microchannels and microcavities, which are etched from the walls, would also have hydrophilic surfaces.

Regarding claim 3 Mian et al. discloses all the claim limitations as set forth above as well as the collection wherein wherein at least one of said devices comprises

a) at least two of said sets of microchannel structures, and/or

b) only one set of microchannel structures, with the proviso that the collection comprises two or more devices which are different with respect to the kind of sets they carry. (See Fig. 17L where device contains more than one layer and set of microchannel structures).

Regarding limitations recited in claim 4 which are directed to a manner of operating disclosed collection, it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See Ex parte Thibault, 164 USPQ 666, 667 (Bd. App. 1969) that states "Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim."

Regarding claim 5 Mian et al. discloses all the claim limitations as set forth above as well as the collection wherein L is selected amongst biotin-binding compounds and streptavidin-binding compounds, respectively, or vice versa. (See Col 43 Lines 30-37 biotin binding streptavidin is used).

Regarding claim 6 Mian et al. discloses all the claim limitations as set forth above as well as the collection wherein L has two or more binding sites for B. (See Col 43 Lines 30-37 biotin binding streptavidin is used and it is inherent that streptavidin has more than one binding site for biotin).

Regarding claim 7 Mian et al. discloses all the claim limitations as set forth above as well as the collection wherein

(a) that each set on a device is grouped into one or more groups of fluidly equivalent microchannel structures, and (See Fig. 17L where sets on each layer are groups of fluidly equivalent microchannel structures) and

(b) that each group is located to a particular subarea of the device. (See Fig. 17L where each layer is a subarea of the device and contains a group)

Regarding claim 8 Mian et al. discloses all the claim limitations as set forth above as well as the collection wherein said reaction microcavity in at least one of said microchannel structures in the upstream direction is connected to a volume- metering unit. (See Fig. 13B and Col. 26 Lines 15-24).

Regarding claim 9 Mian et al. discloses all the claim limitations as set forth above as well as the collection wherein said volume-metering unit is part of an inlet arrangement for liquid. (See Fig. 13B and Col. 26 Lines 15-24)

Regarding claim 10 Mian et al. discloses all the claim limitations as set forth above as well as the collection wherein said reaction microcavity in at least one of said microchannel structures in the upstream direction is connected to a volume-metering unit and wherein said volume-metering unit within at least one of said group(s) is part of a distribution manifold for distributing liquid to the reaction microcavities of the group, with the proviso that each of said at least one group comprises two or more microchannel structures. (See Fig. 13B and Col. 26 Lines 15-24 where multiple samples are dispensed to a group of microchannels using volume-metering units).

Regarding claim 11 Mian et al. discloses all the claim limitations as set forth above as well as the collection wherein the inner wall of each of said volume-metering units has a sufficient hydrophilicity for said unit to filled by capillarity once an aqueous liquid have entered the unit, and b) a valve at its outlet end,. (See Col. 26 Lines 15-24 where volume metering units have appropriate specific surface properties and Col. 14

Lines 45-55 where hydrophilicity is a surface property and Col. 17 Lines 38-41 where fluid movement is controlled by valves).

Regarding claim 12 Mian et al. discloses all the claim limitations as set forth above as well as the collection wherein at least one of the solute S and its affinity counterpart ACs, and/or at least one of the binder B and the ligand L comprise a structure selected from the group of amongst peptide structure consisting of including poly/oligo-peptide and protein structure, carbohydrate structure, lipid structure including steroid structure, nucleotide structure including nucleic acid structure, and polymeric structure. (See Col. 43 Lines 30-34).

Regarding limitations recited in claim 12 which are directed to a manner of operating disclosed collection, it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See Ex parte Thibault, 164 USPQ 666, 667 (Bd. App. 1969) that states "Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim."

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mian et al. (US 6,319,469) as applied to claims 1, 3-12 and 15 above.

Regarding claim 2, Mian et al. discloses all of the claim limitations as set forth above, but the reference does not explicitly disclose the collection wherein at least one of the sets of the collection have a binding capacity difference with a factor $\geq$ 1.2 compared to the binding capacity for the set having the lowest binding capacity. Altering the binding capacities in different sets of microchannels/microcavities allows for more specific reaction and analysis of a wide range of sample types and concentrations and the precise binding capacity differences would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed binding capacity difference factor cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the binding capacity difference factor in the apparatus of Mian et al. to obtain the desired analytic and reactive capabilities of the device. (In re Boesch, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223).

5. Claims 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mian et al. (US 6,319,469) as applied to claims 1-12 and 15 above in view of Jacobs et al. (US 2002/0095073)

Regarding claims 13 and 14 Mian et al. discloses all the claim limitations as set forth above as well as the collection wherein said solid phase is in a dry state (See Col. 39 Line 65- Col. 40 Line 2 where disk is dried) but does not disclose the collection comprising in addition to the solid phase one or more bed preserving agents or wherein at least one of said one or more bed-preserving agents is a microcavity adherence agent.

Jacobs et al. describes the use of a bed preserving agents wherein bed-preserving agents is a microcavity adherence agent. (See [0019] where cross-linked straptavidin is immobilized as a preserving agent)

It would have been obvious to one of ordinary skill in the art at the time of invention to use the bed preserving agent of Jacobs in the collection of Main because doing so helps preserve and stabilize the biological activity of the device. (See Jacobs [0019]).

Response to Arguments

Applicant's arguments filed 04/20/2009 have been fully considered but they are not persuasive. Applicant argues that “Mian not only fails to teach, suggest, or provide an apparent reason for such hydrophilicity, but instead teaches away from such a configuration. Mian discloses the use of a solid phase having a hydrophobic surface

(col. 43, lines 30-40) by employing polystyrene-coated paramagnetic particles. The skilled artisan recognizes that polystyrene is a hydrophobic material and based on Mian would avoid hydrophilic surfaces as with the claimed invention." It is the examiner's position that Mian does in fact teach a solid phase walled microcavity having hydrophilic surfaces. Specifically Mian teaches increasing hydrophilicity of a solid phase wall of a reaction microcavity in order to change the functionalities of said microcavity. It is noted that while the beads as described may be partially formed from a hydrophobic polystyrene, the streptavidin may also be bound directly to solid phase walls (See Col. 43 Lines 35-38) which may be made hydrophilic as described above.). In other words, since the walls are modified to have hydrophilic groups, the microchannels and microcavities, which are etched from the walls, would also have hydrophilic surfaces and applicants have not provided any clear evidence otherwise.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN M. HURST whose telephone number is (571)270-7065. The examiner can normally be reached on Mon. - Thurs. 6:30-5:00; Every Fri. off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571)272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. H./

Examiner, Art Unit 1797

/Michael A Marcheschi/

Supervisory Patent Examiner, Art Unit 1797